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| 10/802,432 | 03/17/2004 | Ulrich Certa | 21574 | 4051 |

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| EXAMINER |
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BRUSCA, JOHN S

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| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/802,432

Applicant(s)

CERTA ET AL.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☒ Claim(s) 7, 12 and 13 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/17/2004, 7/8/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species:

1) EPO species of protein (claims 7 and 13)

2) IFN species of protein (claims 7 and 13)

2. The species are independent or distinct because the species are drawn to mutually exclusive proteins with different structures and different biological functions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-6 and 8-12 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. During a telephone conversation with Dennis P. Tramoloni on 18 May 2006 a provisional election was made without traverse to prosecute the invention of IFN, in Markush-type claims 7 and 13. Affirmation of this election must be made by applicant in replying to this Office action.

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No claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. It is noted that in the telephonic interview of 18 May 2006, a preliminary election of a combination of sequences was made, consisting of SEQ ID NOS: 1-29. Upon further consideration a requirement for election of a specific combination of SEQ ID NOS will not be required for examination of claim 8.

Information Disclosure Statement

6. In the Information Disclosure Statement filed 08 July 2005, references C17, C18, and C19 have not been indicated as considered because the list of references does not include the required information in the citation of the reference as required in 37 CFR 1.98(b)(5). Consequently the references have been listed as not considered in the signed copy of the list of references attached to this Office action. If the applicants provide a list of the claims in compliance with 37 CFR 1.98(b)(5) in response to this Office action, the references will be considered under 37 CFR 1.97(f), and a signed copy of the list of references indicating consideration of the missing references will be provided to the applicants without the necessity of the applicants filing a second Information Disclosure Statement.

Claim Objections

7. Claim 7 is objected to because of the following informalities: The claim recites the term "claims" and should be amended to recite "claim." Appropriate correction is required.
8. Claim 7 is objected to because of the following informalities: The claim recites the term "TNF" and should be amended to recite "IFN." Appropriate correction is required.
9. Claim 12 is objected to because of the following informalities: The claim recites the term "of" twice in line 3. Appropriate correction is required.
10. Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 13 depends on itself. For the purpose of examination the claim has been assumed to depend from claim 12.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
12. Claims 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-11 recite the limitation "the modified protein" in claim 9, line 4. There is insufficient antecedent basis for this limitation in the claim.

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Claims 12 and 13 are indefinite for recitation of the phrase “known modulator” in claim 12, line 2 because it is not clear to whom and when the referred to modulator is known. The rejection would be overcome by deletion of the term “known.”

For the purpose of examination, the claims have been assumed to incorporate the suggested amendments.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Certa et al.

The claims are drawn to a method of comparing levels of gene transcription by use of a microarray in cells treated with a compound.

Certa et al. shows on pages 107-108 methods of treating cells with and without interferon alpha, followed by analysis of gene expression in the cells by use of microarrays of oligonucleotide probes. Tables 2 and 3 detail the results of the assays and show a list of genes that are induced by interferon alpha.

Claim Rejections - 35 USC § 103

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1, 4-7, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Certa et al. in view of Bailon et al. (reference C1 in the Information Disclosure Statement filed 17 June 2004).

The claims are drawn to a method of comparing levels of gene transcription by use of a microarray in cells treated with a compound. In some embodiments the claims are drawn to a compound that is pegylated interferon, and ratios of activity of modified and unmodified compound are determined.

Certa et al. shows on pages 107-108 methods of treating cells with and without interferon alpha, followed by analysis of gene expression in the cells by use of microarrays of oligonucleotide probes. Tables 2 and 3 detail the results of the assays and show a list of genes that are induced by interferon alpha. Certa et al. shows consideration of the ratio of induction of genes in cells that have been treated with interferon on page 108, column 2. Certa et al. does not compare the effect of pegylated and unpegylated interferon on gene expression.

Bailon et al. shows in the abstract and throughout the synthesis and bioassay of pegylated interferon. Bailon et al. shows that pegylated interferon has increased stability when injected in rats when compared to normal interferon in figure 5, and that pegylated interferon has increased antitumor activity when injected into mice when compared to normal interferon in Figure 4.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the assays of gene expression of Certa et al. by comparison of

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normal interferon and pegylated interferon because Bailon et al. shows that pegylated interferon has superior pharmacological and therapeutic properties when compared to normal interferon, and comparison of the effect of pegylated and normal interferon on gene expression would provide information regarding similarity of gene transcriptional effects of pegylated interferon to normal interferon.

17. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Certa et al. in view of Turri et al. in light of GenBank Accession No. U22970.

The claims are drawn to a method of comparing levels of gene transcription by use of a microarray in cells treated with a compound. In some embodiments the assay includes transcription of SEQ ID NO: 3.

Certa et al. shows on pages 107-108 methods of treating cells with and without interferon alpha, followed by analysis of gene expression in the cells by use of microarrays of oligonucleotide probes. Tables 2 and 3 detail the results of the assays and show a list of genes that are induced by interferon alpha. Certa et al. does not show assay of SEQ ID NO:3.

Turri et al. shows that transcription of human gene 6-16 is induced by interferon in the abstract and throughout. GenBank Accession No. U22970 establishes that the human gene 6-16 disclosed in Turri is the same as Accession No. U22970, which is equated in the instant sequence listing with SEQ ID NO:3.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Certa et al. by inclusion of human interferon inducible gene 6-16 because Turri et al. shows that human gene 6-16 is an interferon inducible

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gene and inclusion of human gene 6-16 would allow for a more complete assay of those genes whose transcription are modulated by interferon.

18. Claims 1, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Certa et al. in view of Kumar-Sinha et al.

The claims are drawn to a method of comparing levels of gene transcription by use of a microarray in cells treated with a compound. In some embodiments the effect of interferon on transcription of genes is assayed in the presence and absence of a second compound.

Certa et al. shows on pages 107-108 methods of treating cells with and without interferon alpha, followed by analysis of gene expression in the cells by use of microarrays of oligonucleotide probes. Tables 2 and 3 detail the results of the assays and show a list of genes that are induced by interferon alpha. Certa et al. does not show assay of the effect of interferon on transcription of genes in the presence and absence of a second compound.

Kumar-Sinha et al. measures the effect of a combination of interferon and TRAIL on gene expression by use of microarrays to determine cross-talk between signaling pathways of TRAIL and interferon. Kumar-Sinha et al. shows results of gene expression of cells treated with combinations of TRAIL and interferon in Figures 4, 7, and 8.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the assay of the effect of interferon on gene expression of Certa et al. by comparison of the effect of interferon with and without TRAIL because Kumar-Sinha et al. shows that such analysis allows for elucidation of cross talk between the signaling pathways of interferon and TRAIL.

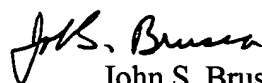
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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 16 September 2006
John S. Brusca
Primary Examiner
Art Unit 1631

jsb